8 PREMARKET NOTIFICATION SPECIAL 510(K) SUMMARY

Sponsor:	Shared P.E.T. Imaging, LLC 4912 Higbee Avenue NW, Ste 100 Canton OH 44718 Telephone: (330) 491-0480 Fax: (330) 491-0488 Contact: Marc A. Simms, Director of Information Technology
Proprietary Name:	Clarity Fusion
Common Name:	Clarity Fusion
Classification Name:	System, Image Processing, Radiological
Reference Number:	§892.2050
Owner/Operator Number:	9056369
Establishment Registration Number:	3004082056
Listing Status:	Active
Proposed Regulatory Class:	Class II
Device Product Code:	LLZ
Panel / Code:	Radiology
Reason for Special 510(k):	Establish Substantial Equivalence to a previously marketed predicate device, Clarity PET. The Clarity PET (K032866) is also manufactured by Shared PET Imaging. This SPECIAL 510(k) merely adds a module to Clarity PET for enhanced diagnostic image quality. The intended use and indications for are not changed from the original 510(k).

- **Device Description and Intended Use:**

  Clarity Fusion is an option within the Clarity PET system so the end-user may differentiate between the two different applications within the same software program. This viewing of fused images is the ability to see the same datasets, as if they were being viewed independently, overlapped with each others. These fused images will allow a physician to look at two different datasets from different modalities. This is common medical practice that has now been computerized.

- **General Safety and Effectiveness Concerns:**

  The device labeling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device. Serving primarily as an aid in image display, this device has no direct adverse effect on health as the results are to be integrated into all of the information a physician will use to form a final interpretation.

- **Substantial Equivalence:**

  As required for a special 510(k), the Clarity Fusion has the identical indications as the Clarity PET and software validation/verification and a Declaration of Conformity were submitted to demonstrate substantial equivalence.

- **510(k) Cleared Indications for Use:**

  To detect or image the distribution of radionuclides in the body or organ, using the following techniques:

  - Multiplanar Reconstruction (MPR)
  - Maximum/Minimum Intensity Projection (MIP)
  - Image Contrast Manipulation
  - Automatic registration with Mutual Information Technique

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Shared P.E.T. Imaging, LLC
% Mr. Russ Pagano
Official Correspondent
M Squared Associates, Inc.
719 A Street, NE
WASHINGTON DC 20002

Re: K042692
Trade/Device Name: Clarity Fusion
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 29, 2004
Received: September 30, 2004

Dear Mr. Pagano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

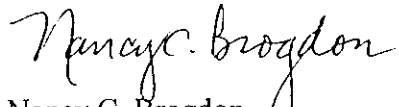
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K042692

Device name: Clarity Fusion

Indications for use:

To detect or image the distribution of radionuclides in the body or organ, using the following techniques:

- Multiplanar Reconstruction (MPR)
- Maximum/Minimum Intensity Projection (MIP)
- Image Contrast Manipulation
- Image Zoom Manipulation
- Automatic registration with Mutual Information Technique

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF cdrh, Office of Device Evaluation (ODE)

Prescription use X (Per 21 CFR801.109) OR Over-the Counter use_____ (Optional format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042692